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NIAID Phase III HIV Vaccine Trial to Determine Correlates of Protection Will Not Proceed

Phase III Trial in Thailand to Determine Efficacy Will Be Supported by NIAID through a Combined NIAID-DoD Program

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the U.S. Army Medical Research and Materiel Command (USAMRMC) of the Department of Defense (DoD), support a broad, comprehensive HIV/AIDS research and development program. Two recent decisions will substantially contribute to a coordinated and comprehensive U.S. government effort to develop preventive HIV vaccines.

DoD HIV Research and Development Program is Transferred to NIH

On January 4, 2002, the White House Office of Management and Budget directed the transfer of oversight and management for the DoD HIV Research and Development Program of USAMRMC to the NIH. NIAID, which has the primary responsibility for HIV/AIDS research within the NIH, will assume responsibility for this program beginning October 1, 2002. Both the NIH and USAMRMC are committed to maintaining and building on the various strengths of each program. The Henry M. Jackson Foundation for the Advancement of Military Medicine, a private, non-profit organization that works closely with the Walter Reed Army Institute for Research (WRAIR), a subordinate laboratory of USAMRMC, will be a resource for both programs.

NIAID and USAMRMC have a common goal: to prevent the further spread of HIV/AIDS by developing safe and effective vaccines, other prevention strategies and innovative HIV treatments. The research activities of both groups are complementary and will be effectively integrated. The major difference between the two is the constituencies they serve: the USAMRMC research program primarily serves young, healthy adults on active military duty who are subject to worldwide deployment, while the NIAID research program serves all civilian age groups and addresses all HIV-associated conditions, such as opportunistic infections and other AIDS complications. NIAID will continue to support HIV research and development that is deemed relevant and supportive of the military mission.

USAMRMC's experience conducting international drug and vaccine development and testing and their established collaborative ties in many parts of the world will enhance NIAID's expanding international efforts. In turn, USAMRMC programs will benefit from NIAID's vast HIV/AIDS pre-clinical research program, which is integrated into NIAID's comprehensive HIV/AIDS research effort.

Since 1993, NIAID and USAMRMC have collaborated significantly on complementary research programs. Most recently, NIAID provided funds to USAMRMC to renovate and construct specialized facilities designed for HIV vaccine production. The two Institutes are also collaborating on a large international clinical trial of IL-2 in people infected with HIV. By formally integrating the experience, expertise, research infrastructure and resources of both Institutes, the merger will ensure the U.S. government HIV research effort is comprehensive, efficient and coordinated.

Phase III HIV Vaccine Efficacy Trial in Thailand Will Continue

Until recently, NIAID and USAMRMC had proposals underway to begin large-scale, phase III HIV vaccine efficacy trials in the near future. Both trials were to test similar "prime-boost" vaccine combinations (a canarypox-virus-based primer vaccine followed by a gp120 subunit booster vaccine), although the vaccines were slightly different, the trials were designed to answer different questions and were to take place in different populations. During fiscal year 2003, NIAID will support the current USAMRMC research program, including its planned prime-boost vaccine efficacy trial in Thailand scheduled to commence in 2002.

However, NIAID will not proceed with a three-arm phase III HIV vaccine efficacy trial, known at HVTN 501, which was under consideration. That decision, made by NIAID and HVTN leadership, in consultation with Aventis Pasteur and VaxGen, the manufacturers of the vaccine candidates, was based on recently learned preliminary immunogenicity results of a phase II trial (HVTN 203) of its prime-boost candidates.

HVTN 203 is designed to further examine the safety and immunogenicity of two experimental HIV vaccines, the canarypox-virus-based vaccine known as ALVAC-HIV (vCP1452) and a gp120 subunit vaccine known as AIDSVAX®B/B[2], given alone or in combination. HVTN 501 was predicated on volunteers in HVTN 203 achieving a pre-determined level of CD8 cellular immune response as measured by a newly developed ELISPOT assay. That information would help determine whether the level of cellular immunity is correlated with vaccine-induced protection against HIV. Antibody response in HVTN 203, although not yet evaluated, is expected to be at the same high rate as observed previously in studies of this combination and of AIDSVAX alone. Preliminary analysis of data from HVTN203 demonstrated that the percentage of volunteers with a detectable ELISPOT signal would likely be too low to provide a valid immune correlates analysis in HVTN 501. Thus, it would not be scientifically sound to proceed with HVTN 501 as currently designed.

The results from HVTN 203 and the decision not to proceed with HVTN 501 does not mean the vaccines are not efficacious, because it is not known which immune assay may eventually be shown to correlate with protection in humans. For this reason, the NIAID fully supports the plans of USAMRMC and its colleagues in Thailand to evaluate the efficacy of a similar vaccine combination, ALVAC-HIV (vCP1521) and AIDSVAX™B/E, which both incorporate envelope antigens from the predominant circulating HIV (CRF_AE_01) in Thailand.

Because HVTN 203 was designed to address other important questions, HVTN 203 will continue to completion so final data can be collected and analyzed by the end of 2002. Additional data from HVTN 203 will not likely reverse the decision not to proceed with HVTN 501 as designed. However, additional data will provide important information about the safety, immunogenicity and the timing of the prime-boost combination.

NIAID and the HVTN will continue to study the ALVAC-HIV (vCP1452) vaccine. HVTN 026 is evaluating the safety and immunogenicity of that vaccine and a gp120 MN vaccine in populations outside the United States. Additionally, a trial designed to evaluate high doses of ALVAC-HIV (vCP1452) is ongoing (HVTN 039) and a trial of that vaccine and a lipopeptide (HVTN 042) is pending. Results from HVTN 203 and other studies and discussions with stakeholders at domestic and international sites will help guide decisions regarding the future development and testing of canarypox HIV vaccine candidates.

NIAID acknowledges the commitments of Aventis Pasteur and VaxGen to the development of an HIV vaccine and their continued involvement in the trial to assess the efficacy of their prime- boost vaccine strategy in Thailand. NIAID will continue to support research and development to advance these products.

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NIAID is a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

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